UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF RALPH ZIPPER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain opinions of Ralph Zipper, M.D.

INTRODUCTION

Dr. Zipper has offered expert opinions on Defendants' Prosima and Prolift devices.[1] *See* Exhibit B, Expert Report on Prosima ("Prosima Rep."); Exhibit C, Expert Report on Prolift and Prolift + M ("Prolift Rep.").[2] He is a pelvic surgeon and urogynecologist in Florida who has experience in treating pelvic organ prolapse and severe urinary incontinence. *See generally* Exhibit D (Curriculum Vitae). Plaintiff, however, hopes to elicit testimony from Dr. Zipper about topics that are entirely outside his professional education, training, and experience and

[1] A plaintiff who was implanted with Defendants' TVT-O device has designated Dr. Zipper as a general expert in her case. *See* Exhibit A. Dr. Zipper has not produced *any* expert reports on the TVT-O device in this Wave, however, and he should therefore be excluded as an expert on TVT-O in that case on this ground alone.

[2] No plaintiff in this wave has designated Dr. Zipper as a general expert on Prolift + M. Defendants will therefore refer to Dr. Zipper's combined Prolift and Prolift + M Report as the Prolift Report.

therefore outside his area of competence. Moreover, his general opinions are unreliable and largely irrelevant.

Specifically, the Court should preclude Dr. Zipper from testifying about the following:

- Alleged design defect opinions concerning mesh degradation, contraction, and extrusion that require biomaterials expertise that Dr. Zipper does not have;
- Alleged design defect opinions that are not supported by application of a reliable methodology;
- Alleged defective warnings contained in the Prosima and Prolift Instructions for Use ("IFU") that are outside of his expertise or that are not supported by a reliable methodology;
- "Safer" alternative products whose comparative safety and efficacy have not been quantified;
- Opinions about Ethicon's alleged knowledge, state of mind and bad acts; and
- Opinions regarding Ethicon's alleged fraud on the FDA.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Zipper. While Dr. Zipper may be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

Dr. Zipper opines that: 1) the Prosima and Prolift were defectively designed; 2) there were safer alternative products; 3) the warnings contained in the Prosima and Prolift IFUs and other labeling were inadequate; 4) the Defendants were aware of the undisclosed risks; and 5) Defendants committed fraud on the FDA. Each of these opinions is flawed and should be excluded.

I. Dr. Zipper's Opinions That The Prosima And Prolift Were Defectively Designed Are Unreliable.

"Expert opinions premised upon speculation and conjecture are insufficient to create a genuine issue of material fact to survive summary judgment." *Dana Corp. v. Am. Standard, Inc.*, 866 F. Supp. 1481, 1499 (N.D. Ind. 1994). An expert's simple *ipse dixit* is insufficient to establish a matter; rather, the expert must explain the basis of his statements to link his conclusions to the facts. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011).

Dr. Zipper opines that Prosima is defective because it causes inflammation, infection, erosion, scarring, and pain; its Gynemesh PS material causes foreign body reaction. (Prosima Rep. 96-100). Notably, Dr. Zipper fails to link these *injuries* to any specific defect in the Prosima device. *See id.* Dr. Zipper also opines that the Prolift was defective because it is a foreign body that degrades, contracts, and becomes inelastic, causing inflammation, oxidation, and scarring. (Prolift Rep. at 167-70). Additionally, Dr. Zipper states that the Prolift's pore size was too small to prevent bridging fibrosis, and that the method of implanting Prolift, an "armed-mesh" with a "blind trocar pass method," was defective. (*Id.* at 172, 179). As further detailed below, Dr. Zipper's opinions regarding these supposed defects are not based on any reliable methodology but are instead mere *ipse dixit.* Moreover, he lacks the requisite expertise to opine regarding certain characteristics of the Prosima and Prolift.

1. Dr. Zipper is not qualified to opine on biomaterial properties of mesh.

Dr. Zipper is neither qualified to opine, nor does he have evidence to support, any opinion addressing the biocompatibility characteristics of the mesh used in the Prosima and Prolift. Dr. Zipper is not qualified by education, training, or experience to opine on biomaterials science issues, including, without limitation, polypropylene mesh degradation, shrinkage, contraction, and porosity. As he previously testified in another mesh case, he does not have "an engineering degree in materials science," nor has he "attend[ed] classes in materials science when in training." *Hammons v. Ethicon, Inc., et al.*, Sept. 26, 2015 Deposition of Ralph Zipper, M.D. ("9/26/15 Dep.") at 209:1-3, attached as Exhibit E. Although Dr. Zipper is a skilled surgeon, he admittedly is not an expert in biocompatibility issues. 9/26/15 Dep. at 208:3-4 ("I do not represent myself as an expert in materials science."). He does not have a demonstrated background in polymer chemistry or biochemical or biomechanical engineering, and his disclosed background indicates that he has never performed any bench research with respect to polypropylene. *See* Exhibit D, Zipper Curriculum Vitae. Dr. Zipper previously testified that he has not conducted one study on the contraction or shrinkage rates of mesh. 9/26/15 Dep. at 248:9-11. He has never performed a study on mesh degradation. *See id.* at 248:12-14. Dr. Zipper's only basis for his biomaterials opinions comes from his own idiosyncratic physical examination of the mesh as a practicing urogynecologist—not from any testing. His lack of expertise in this area necessarily impacts the permissible scope of his testimony. *See Johnson & Johnson v. Batiste*, 2015 WL 6751063, at *6, *9 (Tex. App.—Dallas Nov. 5, 2015, pet. pending) (argument that mesh degrades was legally insufficient where plaintiff's expert admitted that "there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient").

Dr. Zipper has previously testified that he has "worked closely" with engineers in the past to develop a medical device. 9/26/15 Dep. at 109:17-110:11. But Rule 702 of the Federal Rules of Evidence does not allow a witness to offer scientific, technical, or other specialized knowledge outside of his own area of expertise merely because he has spent time with potential experts in other fields. Indeed, Rule 702 states that "[a] witness who is qualified as an expert" may testify if "*the expert's* scientific, technical, or other specialized knowledge" so qualified him. Fed. R. Civ. P. 702 (emphasis added). Rule 702 does not allow a witness to offer opinions based upon someone else's knowledge, skill, experience, training, or education. The fact that Dr. Zipper has "worked closely" with engineers does not make him a biomaterials expert.

Despite his lack of specific expertise, Dr. Zipper offers several opinions concerning the biomaterial properties of polypropylene mesh, most of which he simply regurgitates from the literature which he grossly misinterprets:

- "[V]aginal implantation of [Prolift], composed of polypropylene, results in acute and chronic inflammation, degradation, contraction, and loss of elasticity when implanted in the human vagina. . . . The vaginal implantation of polypropylene, a material that degrades, contracts, and becomes inelastic is unreasonably dangerous for implantation in the vagina; [t]he polypropylene material of [Prolift] is defective." (Prolift Rep. at 170).

- "PROLIFT's GYNEMESH PS fostered bridging fibrosis, [and] the pore size of GYNEMESH PS was significantly too small to prevent bridging fibrosis with resultant unreasonably dangerous contraction." (Prolift Rep. at 172).

- "[T]he mesh implants included with [Prolift] consistently contracted to an unpredictable size, lost nearly all elasticity, were provided in a single size even though no two female pelvises are the same size, and that these troublesome characteristics of the mesh made the results of the POP surgery unpredictable, causes substantial increases in POP surgical morbidity and reoperation, harming both women and their families." (Prolift Rep. at 175).

- "Prior to the introduction of PROLIFT, acute inflammation, chronic inflammation, infection, and contraction associated with transvaginal mesh surgery was confined to the place of surgery, the vagina. The PROLIFT device and method pulled all these problems out of the pelvis, by definition, pulled all of these problems through the muscles of the pelvis, around the bladder and rectum, and into the groin and buttock. . . .Many if not all

of the above noted novel complications caused by PROLIFT are associated with passage of the mesh arms." (Prolift Rep. at 181-82).

- "[T]he PROSIMA device and method combined a defective synthetic transvaginal implant, and implant prone to bodily injury including severe inflammation, infection, erosion, scarring and pain with an experimental vaginal splint that was similar in form, fit (although defectively fit), and function to a pessary, a medical device associated with bodily insult including, inflammation, infection, and ulceration." (PROSIMA Rep. at 96).

- "[F]or numerous causes including but not limited to the severe and chronic foreign body reaction associated with transvaginal polypropylene mesh, the poor post-implantation compliance of polypropylene mesh with resultant material tissue mismatch, the known high and difficult to treat incidence of de novo dyspareunia associated with the transvaginal implantation of polypropylene mesh and, more exactly, Gynemesh PS, the high incidence of mesh erosion and contraction associated with Gynemesh PS, and the insufficient [pore] size of Gynemesh PS . . . the PROSIMA Gynemesh PS material was defective." (Prosima Rep. at 104-105).

In other mesh litigation, this Court has closely scrutinized experts' qualifications to opine about biomaterial properties and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.W. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). In at least one other case, the plaintiff, recognizing the insufficiency of her expert's qualification to opine on biomaterials, simply conceded that her expert would not offer such testimony at trial. *See Eghnayem v. Bos.*

Scientific Corp., 57 F. Supp. 3d 658, 680 (S.D. W. Va. 2014) (upon defendant's challenge to expert doctor's opinions as to "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design, and marketing," "plaintiffs conceded that Dr. Margolis will not be offering these opinions at trial"). Similarly, in the present case, Dr. Zipper's lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh, including mesh degradation and contraction or the effect of mesh on human tissue.

2. Dr. Zipper's opinions are unreliable.

Even if Dr. Zipper were qualified to testify about biomaterial properties of polypropylene mesh—and he is *not*—his opinions concerning degradation, contraction, shrinkage, and porosity are not supported by a reliable methodology. Dr. Zipper admits that he still uses polypropylene mesh today in abdominal sacrocolpopexies—repairs of pelvic organ prolapse—in particular, a mesh called Alyte Y. March 20, 2016 Deposition of Ralph Zipper, M.D. ("3/20/16 Dep.") at 41:21-42:19, attached as Exhibit F. Dr. Zipper believes that analysis of randomized trials is the highest level of scientific evidence as to the safety of a product, 3/20/16 Dep. at 152:18-153:8, and criticizes randomized trials of Ethicon's products 3/20/16 Dep. at 153:20-221:19. He also faults Ethicon for allegedly providing misleading information to the FDA. (Prosima Rep. 93-94; Prolift Rep. at 40-41, 43-44, 47, 50, 55, 60, 65). Based upon these factors, Dr. Zipper has concluded that the Prosima and Prolift devices were defective and their warnings inadequate.

When it comes to the Alyte Y mesh, however, Dr. Zipper does not apply the same methodology he applies to Ethicon's products. In his deposition for the present cases, Dr. Zipper admitted that he was not aware of any randomized clinical trials on Alyte Y mesh at the time of clearance or approval by the FDA; could not name any prospective clinical data performed on

Alyte Y mesh prior to FDA clearance or approval; admitted that he had not reviewed the regulatory dossier on Alyte Y, including correspondence between C.R. Bard and the FDA regarding Alyte Y, internal memos from Bard, and emails from Bard. 3/20/16 Dep. at 312:4-321:10. He also admitted that he had not asked Bard for its regulatory file, internal memos, or internal emails related to the Alyte Y mesh. 3/20/16 Dep. at 321:11-20. In short, he has not judged Alyte Y mesh, a mesh he uses, by the same standards as he judges Ethicon's mesh.

The Court has noted that "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion." *Sanchez v. Boston Sci. Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014). The Court cautioned, however, that this concern "does have a role in applying *Daubert*" in that the Court considers "whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Id*. (citing *Hoffman v. Monsanto Co.*, No. 2:05–CV–00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007)). The Court concluded that it "will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable," but "will consider the independence of an expert's testimony as evidence that his 'research comports with the dictates of good science.'" *Id*. (citing *Daubert II*, 43 F.3d at 1317).

Indeed, Rule 702 of the Federal Rules of Evidence requires that an expert's testimony be "the product of reliable principles and methods" and that the expert "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(c), (d). Dr. Zipper's methodology here shifts violently when he is not using a product he has been paid to render an

opinion on. The Court should exclude his opinions regarding Prosima and Prolift due to this unreliable methodology. *See Sanchez*, 2014 WL 4851989, at *4; *Mathison v. Bos. Sci. Corp.*, 2015 WL 2124991, at *10-11 (S.D. W. Va. May 6, 2015); *see also In re Zyprexa Prods. Liab. Litig.*, No. 04–MD–1596, 2009 WL 1357236, at *3 (E.D.N.Y. May 12, 2009) (excluding expert's testimony where he had not applied principles and methods reliably to the facts of the case and had "been shockingly careless about the facts in the cases he proposes to opine about: whether weight gain preceded or followed use of Zyprexa").

Further, Courts routinely exclude opinions under *Daubert* where the experts inappropriately extrapolate far beyond the data as Dr. Zipper does here. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that neither "*Daubert* [n]or the Federal Rules of Evidence requires [sic] a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"). Regarding alleged mesh degradation, the polypropylene used in Defendants' products has special antioxidants to resist degradation, and there is no reliable evidence that degradation occurs inside the human body, let alone that any degradation ever caused clinical harm to anyone. Because Dr. Zipper's opinions have no basis other than his *ipse dixit*, the Court should exclude his opinions concerning the purported effect of degradation. *See, e.g., Gen. Elec. Co.*, 522 U.S. at 146.

Dr. Zipper also refers to various modes of mesh failure purportedly experienced at his medical center or documented in the FDA's MAUDE database. (*See* Prolift Rep. at 25-28, 26 n.61). But this Court has previously determined the FDA's MAUDE database to be unreliable. *See Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991 (S.D. W. Va. May 6, 2015) ("BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has 'no bearing on whether BSC provided adequate warnings or whether its

products were defective.' *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible."). The Court should likewise exclude any opinion formed by Dr. Zipper based on data collected in the MAUDE database as unreliable.

II. Dr. Zipper's Opinion That There Were Safer Alternative Products Is Subjective And Not Supported By Sufficient Facts Or Data.

Expert testimony is only admissible under Rule 702 if it is "based upon sufficient facts or data"—*i.e.*, if it "rests on a reliable foundation." See *Huskey*, 29 F. Supp. 3d at 701 (citing Rule 702 and *Daubert*, 509 U.S. at 597).

In the present case, Dr. Zipper opines that there were a number of other alternative products or techniques that were equally effective to treat pelvic organ prolapse than the Prolift. In particular, he opines that "native tissue surgeries provide . . . equivalent quality of life benefits with lower complication rates," and that "safer mesh product[s]," such as Ethicon's Prolene and Ultrapro meshes, C.R. Bard's mesh, and Coloplast's Smartmesh and Restorelle were safer than the Gynemesh used in the Prolift. (Prolift Rep. at 184-85).

As an initial matter, alternative surgeries that do not use the product at issue in any manner do not satisfy plaintiffs' burden of establishing a safer alternative design, and are therefore irrelevant and unhelpful to the jury. By its very nature, a safer alternative must be another product. As this Court has stated:

> [A]n "alternative design must not be an altogether essentially different product." *Torkie*, 739 F.Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Id.; see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03–664, 2006 WL 1148506, *3 (W.D.Wash. Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design").

Hines v. Wyeth, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011); *accord Caterpillar, Inc.*, 911 S.W.2d at 385 (finding that the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable mind could conclude that traditional surgical approaches are *products*.

The notion that the traditional surgical procedures are safer alternatives to Ethicon's products is premised on the assumption that all mesh products are unsafe. Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) (surgical alternative to pedicle screw could not be considered). As explained in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013), "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim. *See also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) (noting in design defect context that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle" and that product liability law does not "impose liability in such a way as to eliminate whole categories of useful products from the market").

Additionally, Dr. Zipper has no basis to support his conclusions regarding safety and efficacy. He did not disclose any testing, calculations, engineering analysis, or publications that supported his opinion. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order, at 16 (S.D. W. Va. Nov. 20, 2014) (excluding expert opinion of Dr. Uwe Klinge regarding safer alternative design where, "[i]n the section of his report specifically addressing alternative design, Dr. Klinge fail[ed] to cite *any* peer-reviewed studies") (emphasis in original) (attached hereto as Exhibit G). The first *Daubert* factor is whether the theory or technique employed by the expert can be and

has been tested. *Daubert*, 509 U.S. at 591-95; *see Watkins v. Telsmith, Inc.*, 121 F.3d 984, 992 (5th Cir. 1997) (proposing alternative design requires more than "conceptualizing possibilities"); *see also Oglesby v. Gen. Motors Corp.*, 190 F.3d 244 (4th Cir. 1999) (affirming exclusion of mechanical engineer's expert testimony where "he did not know the type or composition of the plastic" at issue, failed to ask the manufacturer, analyze or test the part, and did not apply any calculations). Dr. Zipper has failed to satisfy that factor here with respect to safer alternative designs. Although he points to other mesh products that currently exist for different indications, this does not obviate the need for testing of the supposedly safer alternative products. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 860-62 (M.D. Tenn. 2005) ("The plaintiff argues that testing is not required because Mr. Friend's proposed alternative design is already in the marketplace. . . . However, the existence of interlock systems is not at issue in consideration of this prong of the *Daubert* factors. The question is whether Mr. Friend's proposed opinion that the Manitowoc boom truck crane was defectively designed because it lacked such a system is sufficiently reliable that it should be admitted in this case. [Plaintiff's evidence of other devices with interlock systems], even if admissible and proved to be true, does not alter the fact that Mr. Friend did not engage in any testing of his theory.").

Dr. Zipper's testimony does not link his conclusions to the analysis, if any, that he performed to determine that other, undisclosed products are indeed more effective. His theory relies heavily upon his own subjective interpretation, and has not been generally accepted within the relevant scientific community. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (rejecting expert's conclusory statement where it was not accompanied by "any evidentiary citation" or followed by any elaboration of the expert's reasoning); *Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329, 1344 (11th Cir. 2003) ("[A]n

expert's failure to explain the basis for an important inference mandates exclusion of his or her opinion."). Therefore, Dr. Zipper's opinion that safer alternative products exist is unreliable and should be excluded.

III. This Court Should Exclude Dr. Zipper's Opinions Regarding The Adequacy Of The Prosima And Prolift IFUs.

Dr. Zipper contends that the IFUs that accompanied the Prosima and Prolift were defective and failed to provide adequate warnings and information to treating surgeons. (Prosima Rep. at 91-92; Prolift Rep. at 185-89; *see also id.* at 190-97). Dr. Zipper has insufficient expertise in developing warnings-related documents. His curriculum vitae and prior depositions testimony reveal insufficient experience in preparing a medical device IFU and no training concerning FDA regulations related to developing warnings or labeling. Previously, Dr. Zipper admitted that he did not "hold [himself] out as a regulatory expert." 9/26/15 Dep. at 229:14. Now, in his most recent deposition, Dr. Zipper claims that he *is* an expert in labeling standards and in FDA regulatory process, and that he has become such an expert since the mid-2000s or within the last few years—*i.e.*, the time since when he has been hired as an expert witness in mesh cases. 3/20/16 Dep. at 240:9-22; 246:9-16; 249:13-253:17. Not only does this contradict his previous testimony, Dr. Zipper cannot become an expert on FDA labeling simply by virtue of litigation. Consultation in litigation hardly equates to meaningful training or hands-on experience in regulatory warning requirements. *See In re Air Crash Disaster*, 795 F.2d 1230, 1234 (5th Cir. 1986) (expressing skepticism of experience gained by expert through litigation consulting).

Dr. Zipper previously admitted that he worked only "on the corporate side" in assisting others in preparing IFUs and helping to determine "regulatory pathways." This does not qualify him to opine about what is required to be in the Prosima and Prolift IFUs. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob

Shull, on warnings and labels for medical devices: "Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process"); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 550-51 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014) (holding that urogynecologist Dr. Donald Ostergard, although qualified to opine about design of sling in question, was not qualified to opine on product warnings and FDA compliance).

Because Dr. Zipper is not qualified to opine about the adequacy of the warnings at issue here, the Court should exclude his testimony about that subject.

IV. The Court Should Exclude Dr. Zipper's Opinions About Ethicon's Knowledge, State of Mind and Alleged Bad Acts.

The Court should preclude Dr. Zipper from testifying about Ethicon's alleged knowledge and bad acts. Dr. Zipper's reports are rife with statements as to what Ethicon allegedly knew or allegedly did with an alleged state of mind. For instance, Dr. Zipper states that "Ethicon was aware that lightweight and larger pore meshes were needed to reduce shrinkage." (Prosima Rep. at 20; *see also id* at 21-24, 66, 80). He also states that "Ethicon was targeting low skilled surgeons and surgeons not presently using synthetic mesh" and making "misrepresentation[s]" to them. (*Id.* at 55; *see also id.* at 60, 63, 80). Dr. Zipper opines repeatedly on Ethicon's alleged state of mind in his Prolift report, stating, for example, that "Ethicon knowingly opted to not inform surgeons that its product was intended for skilled surgeons, knowingly opted not to perform clinical testing, and knowingly opted not to inform surgeons that it had not performed such testing." (Prolift Rep. at 51; *see also id.* at 55, 57, 92, 95, 104-05, 112, 118, 133, 137, 150, 158, 166-67, 170). There is nothing about Dr. Zipper's experience as a pelvic surgeon that affords him specialized knowledge or clairvoyance to testify about what Ethicon did or did not know or to speculate about what Ethicon supposedly never did. *See, e.g., In re: Diet Drugs*

Prods. Liab. Litig., 2000 U.S. Dist. LEXIS 9037, at *9 (E.D. Pa. 2000) (precluding the plaintiffs' experts from testifying as to the defendants' intent); *In re: Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony"); *BorgWarner, Inc. v. Honeywell Int'l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010) (precluding a party's expert witness from opining about a party's intent). To the extent that Dr. Zipper's opinions are based on his review of documents that Plaintiffs' counsel selectively presented to him, these concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

Recently, this Court precluded another physician from offering similar testimony. In *Lewis v. Ethicon, Inc.*, Case No. 2:12-cv-4301, 2014 WL 186872 (S.D. W. Va. Jan. 15, 2014), this Court found that "expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury" and that although the expert in issue was "qualified as a physician; he is not qualified by 'knowledge, skill, experience, training or education' to opine on Ethicon's state of mind or knowledge." *Id.* at *15. And in *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013), one of the plaintiffs' experts, Dr. Bob Shull, a urogynecologist like Dr. Miklos, intended to testify about "Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Id.* at 610. This Court, however, found as follows:

> While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions – assuming the opinions are otherwise admissible – Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y.

> 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I FIND that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

Id. at 611; *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at *7-8 (S.D. W. Va. Feb. 15, 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert's opinion was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents).

The same is true here. Dr. Zipper testified in his deposition related to these Wave 1 cases that he knows what Ethicon was doing and thinking because "[i]t's in their documents." 3/20/16 Dep. at 271:21. A jury is able to read documents and draw its own conclusions; Dr. Zipper should not be permitted to usurp that function. For the same reasons that this Court precluded Dr. Shull from testifying about such matters, the Court should also preclude Dr. Zipper from testifying about these matters.

V. The Court Should Exclude Dr. Zipper's Opinions That Amount to a Mere Historical Commentary.

The vast majority of Dr. Zipper's reports consists of cumulative historic commentary about Defendants' alleged bad acts—opinions that are improper because they have nothing to do with his expertise. As this Court has noted, such a rehashing of a fact narrative is improper. *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

Such improper testimony includes Dr. Zipper's opinions about Defendants' alleged knowledge, state of mind, and product warnings, which the Court should also exclude for the reasons set forth above. Other examples of opinions beyond Dr. Zipper's expertise that amount

to an impermissible historical commentary include the regurgitation of factual timelines on pages 15-91 of his Prosima report and pages 18-32, 35-166 of his Prolift report.

There is no basis for Dr. Zipper to rehash these alleged factual events, and his testimony should be excluded. *See United States v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) ("Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re: Rezulin*, 309 F. Supp. 2d at 551 (excluding expert testimony intended merely to "provid[e] an historical commentary of what happened"); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y.2005) ("[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence"); *In re: Trasylol*, 709 F. Supp. 2d 1323, 1346-47 (S.D. Fla. 2010) (excluding expert's testimony, including expert's references to defendant's internal documents, finding that the expert was simply "Plaintiffs' advocate rather than expert"); *In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert's report because it "presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory findings, and the deposition testimony of Merck employees").

VI. The Court Should Exclude Dr. Zipper's Opinions That Ethicon Misled or Committed Fraud on the FDA.

Dr. Zipper opines repeatedly in his reports that Ethicon submitted misleading information to the FDA in connection with its devices or was "deceitful" in its correspondence with the FDA. (*See, e.g.*, Prosima Rep. at 93-94 ("Ethicon knowingly provided false information to the FDA to gain a SE determination. . . . Ethicon knowingly provided incorrect, insufficient and deceiving information to the FDA in order to gain rapid clearance for marketing and bypass the PMA process."); Prolift Rep. at 40-41, 43-44, 47, 50, 55, 60, 65 (opining that responses to FDA were

"deceitful")). He even goes so far as to opine that "Ethicon . . . admits that it has been in violation of a federal law," "admits to the misbranding of its PROLIFT device in its Instructions for Use Label," and that "misbranding is a violation of the law." (Prolift Rep. at 67, 73, 76, 79-81, 85-87, 89-90, 99-101, 104).

It is well-established that an expert cannot testify as to an ultimate legal determination such as whether a Defendant has knowingly engaged in behavior that would constitute fraud. *See Woods v. Lecureux*, 110 F.3d 1215, 1221 (6th Cir. 1997) (testimony telling jury what result to reach is unhelpful to the jury; witness's testimony "gives the false impression that he knows the answer to [the deliberate-indifference] inquiry, which depends on . . . mental state. For a witness to stack inference upon inference and then state an opinion regarding the ultimate issue is even more likely to be unhelpful to the trier of fact"); *Dahlin v. Evangelical Child & Family Agency*, No. 01-C-1182, 2002 WL 31834881, at *3 (N.D. Ill Dec. 18, 2002) (holding that an expert cannot testify that certain actions constituted fraud because it "is a quintessential jury determination on which the Court will instruct a jury concerning the factors it is to consider" and because the expert is no "more qualified than an ordinary juror" to determine intent) (collecting cases). This Court has continued to diligently adhere to these principles, directing counsel to "tailor expert testimony at trial" in accordance with these limitations. *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *3 (S.D. W. Va. May 6, 2015). Indeed, this Court has previously specifically precluded an expert from testifying that Ethicon deceived the FDA. *See Lewis v. Ethicon, Inc.*, Case No. 2:12-cv-4301, 2014 WL 186872, at *15 (S.D. W.Va. Jan. 15, 2014). The Court should do the same in this case and bar Dr. Zipper from testifying as to Ethicon's alleged fraud and to the legal determination that Ethicon allegedly violated federal misbranding laws.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Zipper's testimony consistent with the foregoing.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 23558-3824
(304) 414-1800

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

CERTIFICATE OF SERVICE

I certify that on April 21, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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